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May 26, 2004

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APPLICATION NUMBER: *10/746,455*
FILING DATE: *December 24, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/08909*

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

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PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

01/06/2004 WASFAW1 00000060 500815 10746455

01 FC:2001 385.00 DA
02 FC:2202 270.00 DA

PTO-1556
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*U.S. Government Printing Office: 2001 — 481-697/59173

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PTO/SB/05 (05-03)
Approved for use through 04/30/2003. OMB 0651-0032
U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	CRMD-003
First Inventor	NIKOLCHEV, JULIAN
Title	BALLOON CATHETER LUMEN BASED STENT DELIVERY SYSTEMS
Express Mail Label No.	EV 405 279 490 US

APPLICATION ELEMENTS

SEE MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Commissioner for Patents
Mail Stop Patent Application
P.O. Box 1450
Alexandria, VA 22313-1450

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. ☒ Applicant claims small entity status. See 37 CFR 1.27.
3. ☒ Specification *(preferred arrangement set forth below)* [Total Pages: 39]
   - -Descriptive title of the invention
   - -Cross Reference to Related Applications
   - -Statement Regarding Fed sponsored R & D
   - -Reference to sequence listing, a table, or a computer program listing appendix
   - -Background of the Invention
   - -Brief Summary of the Invention
   - -Brief Description of the Drawings *(if filed)*
   - -Detailed Description
   - -Claim(s)
   - -Abstract of the Disclosure
4. ☒ Drawing(s) *(35 U.S.C. 113)* [Total Pages: 13]
5. Oath or Declaration [Total Pages: 1]
   - a. ☒ Newly executed (original or copy)
   - b. ☐ Copy from a prior application (37 CFR 1.63 (d)) *(for continuation/divisional with Box 18 completed)*
     - i. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) Named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b)
6. ☒ Application Data Sheet. See 37 CFR 1.76
7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   - a. ☐ Computer Readable Form (CRF)
   - b. Specification Sequence Listing on:
     - i. ☐ CD-ROM or CD-R (2 copies); or
     - ii. ☐ paper
   - c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & documents(s))
10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney *(when there is an assignee)*
11. ☐ English Translation Document *(if applicable)*
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☒ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. ☐ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other: _____

18. **If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:***

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 60/458,323 filed 3/26/2003

Prior application information: *Examiner:* _____ *Group Art Unit:* _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

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Signature				Date	December 24, 2003

PTO/SB/17 (10-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 716.00

Complete if Known	
Application Number	To Be Assigned
Filing Date	Herewith
First Named Inventor	NIKOLCHEV, JULIAN
Examiner Name	To Be Assigned
Art Unit	To Be Assigned
Attorney Docket No.	CRMD-003

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 50-0815

Deposit Account Name: Bozicevic, Field & Francis LLP

The Director is authorized to: (*check all that apply*)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☐ Charge any additional fee(s) during the pendency of this application.

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	385.00
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
				SUBTOTAL (1)	385.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below		Fee Paid
Total Claims	52	-20** = 32	x 9	=	288.00
Indep. Claims	4	-3** = 1	x 43	=	43.00
Multiple Dependent			0	=	0

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) $ 331.00

**or number previously paid, if greater; For Reissues, see above.

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge – late filing fee or oath	
1052	50	2052	25	Surcharge – late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examination action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive – unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
				Other fee (specify) _____	
				*Reduced by Basic Filing Fee Paid **SUBTOTAL (3) ($)**	0.00

SUBMITTED BY

Name (Print/Type)	Carol M. DeSalle	Registration No. (Attorney/Agent)	39,740	Telephone	(650) 833-7778
Signature				Date	12/24/2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

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APPLICATION INFORMATION

Application Type::	Utility
Title::	BALLOON CATHETER LUMEN BASED STENT DELIVERY SYSTEMS
Attorney Docket Number::	CRMD-003
Request for Non-Publication?::	No
Assignee for Publication::	CardioMind, Inc.
Total Drawing Sheets::	13
Small Entity?::	Small
License US Govt. Agency::	No
Contract or Grant Numbers::	N/A
Sequence Submission?::	No
Computer Readable Form (CRF)?::	No

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REPRESENTATIVE INFORMATION

Representative Customer Number::	24353

CONTINUITY INFORMATION

This application is a::	Non Prov. Of Provisional
> Application One::	60/458,323
Filing Date::	March 26, 2003
This application is a::	Non Prov. Of Provisional
> Application Two::	60/462,219
Filing Date::	April 10, 2003
which is a::	
>> Application Three::	
Filing Date::	
which is a::	
>>> Application Four::	
Filing Date::	

PRIOR FOREIGN APPLICATIONS

Foreign Application One::	
Filing Date::	
Country::	
Priority Claimed::	

EXPRESS MAIL LABEL NO. EV 405 279 490 US

PRELIMINARY AMENDMENT Address to: Assistant Commissioner for Patents Washington, D.C. 20231	Attorney Docket	CRMD-003
	First Named Inventor	Nikolchev
	Application Number	To be assigned
	Filing Date	Herewith
	Group Art Unit	Unassigned
	Examiner Name	Unassigned
	Title:	BALLOON CATHETER LUMEN BASED STENT DELIVERY SYSTEMS

Sir:

This is a Preliminary Amendment to the patent application identified above. Prior to examination of the subject application, please enter the following amendments to the specification and claims:

AMENDMENTS

In the Title

Please replace the title with the following new title:

BALLOON CATHETER LUMEN BASED STENT DELIVERY SYSTEMS

In the Specification

After the title, before the "Field of the Invention" please add the following new paragraph and heading:

CROSS REFERENCE TO RELATED APPLICATIONS

This patent claims the benefit of U.S. Provisional Application S/N 60/458,323, entitled, "Implant Delivery Device," filed March 26, 2003 and U.S. Provisional Patent Application S/N 60/462,219, entitled "Implant Delivery Device II", filed April 10, 2003 - each by Julian Nikolchev.

IMPLANT DELIVERY DEVICE (II)

FIELD OF THE INVENTION

[0001] This invention relates to devices and methods for placing one or more implants such as helical scaffolds or occlusive members into tubular organs or open regions of the body. The implants may be of types that maintain patency of an open anatomical structure, occlude a selected volume, isolate a region, or collect other occlusive members at a site. Included in the description are devices and methods for deploying the various implants, typically without a sheath, in a serial fashion, and with high adjustibility.

BACKGROUND OF THE INVENTION

[0002] Implants such as stents and occlusive coils have been used in patients for a wide variety of reasons. For instance, stents are often used to treat arterial stenosis secondary to atherosclerosis. Various stent designs have been developed and used clinically, but self-expandable and balloon-expandable stent systems and their related deployment techniques are now predominant. Examples of self-expandable stents currently in use are WALLSTENT® stents (Schneider Peripheral Division, Minneapolis, MN) and Gianturco stents (Cook, Inc., Bloomington, IN). The most commonly used balloon-expandable stent is the PALMAZ® stent (Cordis Corporation, Warren, NJ).

[0003] Typically, after balloon angioplasty has been performed, either a self-expandable or balloon-expandable stent is advanced over a guidewire and positioned at the target site. A protective sheath or membrane is then retracted proximally to allow expansion of a self-expanding stent. Alternatively, a delivery balloon may be inflated, thereby expanding the stent.

[0004] Despite improvements in delivery systems, balloon design, and stent design, these over-the-guidewire and/or sheathed self-expanding stent deployment

systems still have their limitations. For instance, sheathed stents tend to move forward when the sheath is pulled back, deploying them imprecisely. The sheathed design also requires that the stent delivery system be larger in diameter and less flexible. Furthermore, for sheathed systems, the interventional procedure may only proceed if the vessel of interest is of sufficiently large diameter to allow sheath placement to avoid significant damage to the luminal surface of the vessel. Moreover, balloon-expandable stents, by virtue of a large diameter and relative inflexibility, are often unable to reach distal vasculature. For both self-expandable and balloon-expandable stent deployment systems, repositioning or step-wise release of the stent are usually not available features. Similarly, occlusive coil placement systems such as systems that deliver detachable platinum coils and GDC® coils also generally do not contain repositionable or step-wise release features.

[0005] Consequently, a smaller diameter (lower profile), repositionable implant deployment device that releases an implant into, or upon, a body region in a more precise, continuous or step-wise fashion, without the use of a sheath or balloon would provide significant benefit to patients with various medical conditions.

SUMMARY OF THE INVENTION

[0006] The present invention is a low profile implant delivery device that may be deployed without a sheath, and is designed to release portions of implants simultaneously or sequentially.

[0007] In one variation, the implant delivery device includes a noninflatable, elongate delivery guide member having a distal end and configuration that allows it to direct at least one implant having an exterior and interior surface to an anatomical treatment site by manipulation by a user. The at least one implant has a delivery diameter prior to its release, is located proximally of the distal end of the delivery guide member prior to release, and has at least one releasable joint configured to maintain at least a section of the at least one implant at the delivery diameter until

release of the at least one releasable joint. The delivery guide member sections that are proximal and distal to the at least one implant also have delivery diameters. These guide member delivery diameters may be substantially equal to the at least one implant delivery diameter prior to implant release.

[0008] The implant may be a helical scaffold, e.g., a stent, in particular, a self-expandable stent, or it may be an occlusive coil. The implant may be symmetric or asymmetric. In some instances, the implant delivers a therapeutic agent.

[0009] The delivery guide member may include a wire and/or a tubular member having a lumen. If desired, a radioopaque marker may be included on the delivery guide to aid with its placement. When designed to include a tubular member, it co-axially surrounds at least a portion of the delivery guide, and works as a tubular actuator configured to release at least one releasable joint upon distal axial movement along the delivery guide member.

[0010] In another variation, the implant delivery device includes an actuator slidably located at least partially within the delivery guide member and is configured to mechanically release at least one releasable joint upon axial movement of the actuator within the delivery guide member. In other variations, the actuator may also release at least one releasable joint upon rotational movement of the actuator, upon the application of fluid pressure in the delivery guide member lumen, or upon application of a suitable DC current to the at least one releasable joint. Release of the releasable joints using any one of the release mechanisms described above may be sequential, if precise positioning is required, or may be simultaneous. Each feature of each variation may be used on any of the other variations.

[0011] The implant delivery device may be included in a system for implant delivery which further employs one or more embolic filters at either the proximal or distal section of the delivery guide, or at both the proximal and distal sections of the delivery guide.

[0012] The system may be used for implant delivery into lumens of tubular organs including, but not limited to, blood vessels (including intracranial vessels, large vessels, peripheral vessels, adjacent aneurysms, arteriovenous malformations, arteriovenous fistulas), ureters, bile ducts, fallopian tubes, cardiac chambers, ducts such as bile ducts and mammary ducts, large and small airways, and hollow organs, e.g., stomach, intestines, and bladder. The implant may be of a design that is of a size that is smaller during delivery and larger after implantation. The design may be used to provide or to maintain patency in an open region of an anatomical structure, or to occlude a site, or to isolate a region (e.g., to close an aneurysm by blocking the aneurysm opening or neck by placement in an adjacent anatomical structure such as an artery or gastrointesinal tubular member), or to corral or collect a number of occlusive devices (e.g., coils or hydratable polymeric noodles) or compositions at a site to be occluded or supported. In another variation, the implant is located in a gap between proximal and distal sections of the delivery guide member. The system may also be employed for implant delivery into solid organs or tissues including, but not limited to, skin, muscle, fat, brain, liver, kidneys, spleen, and benign and malignant tumors. Preferably, the implant is delivered to a target site in a blood vessel lumen.

[0013] In a general aspect, the system is a guidewire-less implant delivery system that includes a noninflatable, elongate delivery guide member having a proximal end and a distal end. The guide member is configured to direct at least one implant having an exterior and interior surface to an anatomical treatment site by manipulation by a user. The at least one implant has a delivery diameter prior to release of the at least one implant and is located proximally of the distal end of the delivery guide member prior to release. The at least one releasable joint is configured to maintain at least a section of the at least one implant at the delivery diameter until release of the at least one releasable joint. The guidewire-less system also has a flexibility and remote directability such that a user may direct the distal end of the

guide member into, and introduce, the at least one implant into a coronary artery solely by manipulation of the delivery guide member from its proximal end.

BRIEF DESCRIPTION OF THE DRAWING(S)

[0014] Figure 1A is a side view of an implant delivery device with a partial cross-section of the distal section of the delivery guide.

[0015] Figure 1B is a cross-sectional view of the delivery guide and implant taken at line 1B-1B in Figure 1A.

[0016] Figure 2 is a side view of an implant delivery device having a tubular member (actuator) attached to the proximal implant end with a partial cross-section of the distal section of the delivery guide.

[0017] Figure 3A is a side view of the implant in Figure 2 being expanded by distally moving the tubular member towards the distal section of the delivery guide.

[0018] Figure 3B is a longitudinal cross-sectional view of a distal implant release mechanism.

[0019] Figures $3C_1$ and $3C_2$ are longitudinal cross-sectional views of an implant delivery device having a mechanical release mechanism for deploying one end of an implant.

[0020] Figures $3D_1$-$3D_3$ are longitudinal cross-sectional views of an implant delivery device having a mechanical release mechanism for independently releasing the implant ends.

[0021] Figures $3E_1$-$3E_4$ are longitudinal cross-sectional views of an implant delivery device having a hydraulic release mechanism for independently releasing the implant ends.

[0022] Figures $3F_1$-$3F_2$ are longitudinal cross-sectional views of a variation of the hydraulic release mechanism described in $3E_1$-$3E_4$.

[0023] Figures $3G_1$-$3G_3$ are longitudinal cross-sectional views of an implant delivery device having a mechanical release mechanism according to another variation of the invention.

[0024] Figure 4 is a longitudinal cross-sectional view of an implant delivery device having a mechanical release mechanism according to yet another variation of the invention.

[0025] Figures 5A-5C are longitudinal cross-sectional views of an implant delivery device having an electrolytic implant release mechanism.

[0026] Figure 5D shows a longitudinal cross-sectional view of an implant delivery device having an electrolytic release mechanism according to another variation of the invention.

[0027] Figure 5E shows a longitudinal cross-sectional view of an implant delivery device having a thermal release mechanism according to one variation of the invention.

[0028] Figures 6A-6D show the general method for serially releasing an implant at a target site.

DETAILED DESCRIPTION OF THE INVENTION

[0029] Described here are devices, systems, and methods for delivering implants into both open and solid regions of the body. The term "region" as used herein refers to luminal structures as well as solid organs and solid tissues of the body, whether in their diseased or nondiseased state. Examples of luminal structures include, but are not limited to, blood vessels, arteriovenous malformations, aneurysms, arteriovenous fistulas, cardiac chambers, ducts such as bile ducts and mammary ducts, fallopian tubes, ureters, large and small airways, and hollow organs, e.g., stomach, intestines, and bladder. Solid organs or tissues include, but are not limited to, skin, muscle, fat, brain, liver, kidneys, spleen, and benign and malignant tumors.

[0030] The device assembly generally includes an elongate, perhaps solid delivery guide, an implant, and one or more implant release mechanisms. Guidewire-less systems are used to deliver the one or more implants. By "guidewire-less" it is meant that the system does not require a guiding device of a diameter less than that of the guide member upon which the implant is delivered to reach a chosen implantation site. Instead, the guidewire-less system is flexible and remotely directable, the remote directability being such that a user may direct the distal end of the guide member into, and introduce, the at least one implant into a coronary artery solely by manipulation of the delivery guide member from its proximal end.

Delivery Guide or Delivery Guide Member

[0031] The delivery guide is elongate and has a comparatively small effective diameter. It has the function of permitting delivery of the implant to a selected site and supporting the implant in a collapsed form during positioning and implantation. The delivery guide is usually noninflatable. It may also be solid, or may have a lumen extending therethrough, depending on such factors as the degree of flexibility required, type of associated release mechanism, the constitution material, and the like. The tip of the delivery guide may be tapered and/or straight, curved, or j-shaped, depending on factors such as physician preference, the anatomy of the tubular organ or region of interest, degree of stiffness required, and the like. The delivery guide may or may not include an outer spring coil, for, e.g., fluoroscopic visualization.

[0032] The delivery guide member and the delivery system into which it is placed desirably serves the function as would a guidewire in, for instance, a cardiac or neurovascular catheterization procedure. The concept that the delivery guide member or system including that guide member and implant(s) is "remotely directable" is to say that the combination of physical parameters of the delivery guide member, implant, and joints are selected to allow advancement of the system much in

the same way as would be a guidewire. Such physical parameters include, for instance, choice of materials, stiffness, size of materials, physical or chemical treatment, tapering (if desired), all in the same way that those physical parameters are selected in designing a cardiovascular or neurovascular guidewire.

[0033] The delivery guide may be made from any biocompatible material including, but not limited to, stainless steel and any of its alloys; titanium alloys, e.g., nickel-titanium alloys; other shape memory alloys; tantalum; polymers, e.g., polyethylene and copolymers thereof, polyethylene terephthalate or copolymers thereof, nylon, silicone, polyurethanes, fluoropolymers, poly (vinylchloride), and combinations thereof. The diameter of the delivery guide may usually be about 0.013 cm to about 0.130 cm (about 0.005 inches to about 0.05 inches), more usually about 0.013 cm to about 0.076 cm (about 0.005 inches to about 0.03 inches), and more usually still about 0.015 cm to about 0.030 cm (about 0.006 inches to about 0.012 inches). In a preferred variation, the diameter of the delivery guide is approximately about 0.020 cm (about 0.008 inches).

[0034] A lubricious coating may be placed on the delivery guide if desired to facilitate advancement of the delivery guide. The lubricious coating typically will include hydrophilic polymers such as polyvinylpyrrolidone-based compositions, fluoropolymers such as tetrafluoroethylene, or silicones. In one variation, the lubricious coating may constitute a hydrophilic gel. Furthermore, the delivery guide may include one or more radioopaque markers that indicates the location of the distal section of the delivery guide upon radiographic imaging. Usually, the marker will be detected by fluoroscopy.

Implants

[0035] The implant itself may be of a shape tailored to achieve a specific purpose. As noted elsewhere, if the purpose of the implant is to provide or to maintain patency of an anatomical structure such as an artery or duct, the implant

shape after implantation is itself tubular. The shape may be symmetric or asymmetric, as the purpose dictates.

[0036] Other shapes, including cage structures, may be used to provide patency to vessels or to act as collecting or coralling structures for occlusive members or materials.

[0037] If the purpose or task is to occlude a lumen or open region, the implant may have the form of an occlusive coil that remains helical after deployment or assumes a random orientation.

[0038] In one variation, the implant for placement into a luminal structure is a helical scaffold, e.g., a stent, but any scaffold shape that maintains patency of a lumen may be used. The stents are typically self-expanding stents, such as described in U.S. 4,768,507 to Fishell et al., U.S. 4,990,155 to Wilkoff et al., and U.S. 4,553,545 to Maass et al. In another variation, the implant is an occlusive member, e.g., an occlusive coil, such as described in U.S. 5,334,210 to Gianturco and U.S. 5,382,259 to Phelps et al.

[0039] The interior and exterior surfaces of the implant may be designed to prevent the activation of pathological processes during or after implant deployment. For example, in the case of a vascular stent, the exterior stent surface may be formed to be smooth to decrease the likelihood of intimal damage upon stent release (which would trigger the inflammatory process and attract atheromatous plaque-forming cells). The interior stent surface may also be smooth to minimize turbulent flow through the stent and decrease the risk of stent thrombosis.

[0040] Important physical properties of the implant to consider include, but are not limited to: length, (stent) diameter in the expanded state, degree of flexibility and lateral stiffness, and the like. These physical properties will be modified to account for such factors as lumen diameter, length of any stenosis, type of luminal structure, or solid organ or tissue involved.

[0041] Metals such as stainless steel and tantalum, or metal alloys such as alloys of nickel and titanium, specifically including superelastic alloys such as NITINOL or Elgiloy which are commonly used by those of skill in the art, may be used to form the implants. However, the implants may also be made from biodegradable polymers, e.g., copolymers of lactic and glycolic acid, or nonbiodegradable polymers, e.g., copolymers of ethylene and vinyl acetate.

[0042] The implants may also include a therapeutic agent. Examples of therapeutic agents that may be used in the implants include, but are not limited to, antibiotics, anticoagulants, antifungal agents, anti-inflammatory agents, antineoplastic agents, antithrombotic agents, endothelialization promoting agents, free radical scavengers, immunosuppressive agents, thrombolytic agents, and any combination thereof. If the implant is a stent, an antithrombotic agent is preferably included.

[0043] Examples of selective antithrombotic agents include acetylsalicylic acid, argatroban, cilostazol, copidogrel, cloricromen, dalteparin, daltroban, defibrotide, dipyridamole, enoxaparin, epoprostenol, indobufen, iloprost, integrelin, isbogrel, lamifiban, lamoparan, nadroparin, ozagrel, picotamide, plafibride, reviparin sodium, ridogrel, sulfinpyrazone, taprostene, ticlopidine, tinzaparin, tirofiban, triflusal, and any of their derivatives.

[0044] The therapeutic agent may be coated onto the implant, mixed with a biodegradable polymer or other suitable temporary carrier and then coated onto the implant, or, when the implant is made from a polymeric material, dispersed throughout the polymer.

[0045] The implant may include a radioactive material. The radioactive material may be selected on the basis of its use. For instance, the material may be included in an implant where the implant is in the form of a stent that is to be situated over a vascular stenosis. The radioactivity lowers the incidence of re-stenosis. Additionally, the radioactivity may serve the function of a tracer, to allow detection

of the location of the implant during the procedure or anytime thereafter. Suitable radioactive tracers include isotopes of gallium, iodine, technetium, and thallium.

Release Mechanism

[0046] In one variation of the generic implant delivery system, as shown in Figure 1A, the implant delivery system includes a delivery guide 100. Delivery guide 100 has a proximal section 102 and a distal section 104. An implant, in this case depicted as a stent 106, surrounds a portion of the distal section 104 of the delivery guide, and is releasably attached to the distal section 104 of the delivery guide. The implant 106, as shown in Figure 1B, is concentrically adjacent to the delivery guide 100. Although I show the stent in Figure 1A and 1B as the implant (106), I depict it in this fashion solely for the illustrative purpose of indicating the siting of the implant 106 on the delivery guide 100 with the distal and proximal implant release mechanism (109, 111). Various implant release mechanisms or structures are discussed in greater detail below.

[0047] Implant 106 is shown to be directly attached to, is contiguous to, the delivery guide 100 at the proximal end 108 of the implant and distal end 110 of the implant. In the system shown in Figure 1A, implant 106 may be secured to the delivery guide 100 by such generic controllably releasable mechanisms as mechanical, thermal, hydraulic, and electrolytic mechanisms, or a combination thereof. Examples of these release mechanisms will be discussed below.

[0048] Consequently, release of the implant 106 from the delivery guide 100 may be achieved through a mechanical detachment process involving, e.g., twisting of the delivery guide, such as described by Amplatz in U.S. 6,468,301, or translational movement of the delivery guide in relation to the implant. Implant release may also be achieved using a thermally detachable joint, such as described in U.S. 5,108,407 to Geremia et al., an electrolytic detachable joint, such as described in

U.S. 5,122,136 and U.S. 5,354,295, both to Gulglielmi et al., or a combination thereof.

[0049] In another variation, and as shown in Figure 2, the system includes a tubular member 200 co-axially mounted on a delivery guide 202. Tubular member 200 may form a component of the delivery guide 202 that cooperates with one or more of the releasable mentioned joints on the implant (209, 211) to release those joints (and therefore, release the implant 204) upon application of a releasing movement, axial or twisting. An implant, e.g., a stent 204, is mounted on a distal section 206 of the delivery guide and the distal end 208 of the tubular member is attached to the proximal end 210 of the stent. The distal end 212 of the stent is attached using a releasable joint 211 to the distal section 206 of the delivery guide 202.

[0050] As mentioned above, I may use a tubular member mounted coaxially about the delivery guide, that slides axially about that delivery guide, as a actuator to release the implant. The outer tubular member may also be used to pre-position the implant. For instance, prior to release, the outer tubular member may be used to expand the implant to therefore obscure its placement, and so to permit adjustment of the placement. Figure 3A shows a stent 300 expanding as tubular member 302 is moved distally on the delivery guide 304, in the direction of the arrow. The stent is then released from the delivery guide. Specifically, the distal end 306 of the stent is released from a distal section 308 of the delivery guide, followed by release of the proximal end 310 of the stent from the distal end 312 of the tubular member. As mentioned above, the stent 300 may be secured to a distal section 308 of the delivery guide by such mechanisms as lock and key arrangements, biocompatible adhesives, soldering, or a combination thereof. Consequently, stent release may be achieved through a mechanical detachment process, a thermal detachment process (e.g., by heat produced from an exothermic reaction), an electrolytic detachment process, or a combination thereof.

[0051] Figures 3B and 3C show yet another variation of a stent release mechanism. In Figure 3B, brackets 314 may be used to couple the stent 300 to the distal section 308 of the delivery guide. Separation of the stent 306 from the brackets 314, e.g., by one of the detachment processes mentioned above, releases the distal end 306 of the stent from a distal section 308 of the delivery guide, allowing the stent distal end 306 to expand in the tubular organ.

[0052] Controllable release of an end of an implant from the delivery guide may be accomplished using the structure of Figure $3C_1$. Brackets 314 couple the stent proximal end 310 to the distal region 312 of the tubular member 313 that forms a portion of the delivery guide. The brackets 314 have a ramped region 316 which are proximally adjacent to an enlarged (and perhaps ball- or barrel-shaped) portion 318 of the delivery guide and bracket arms 320. The delivery guide and stent each have a delivery diameter, and these delivery diameters may be substantially equal prior to release of the stent. When the actuator 305 is moved proximally, as shown by the direction of the arrow, the ball-shaped portion 318 forces the ramped regions 316 of the brackets outward from the delivery guide axis, in a radial fashion, causing the bracket arms 320 to be displaced radially outwardly from the proximal end 310 of the stent, thereby releasing the stent proximal end 310.

[0053] Figure $3C_2$ shows the results of moving the actuator 305 proximally. The clips (316) have rotated as shown due to the force exerted upon the ramps (317) by the ball (318). The implant (320) has expanded in diameter from that found in its undelivered form.

[0054] The actuator may be attached, perhaps with a distal radioopaque coil or directly, to a distal section (not shown) of the guide member.

[0055] Figure $3D_1$, shows a delivery system 319 in which the two ends of the implant 321 may be independently deployed by using an actuator 304 having a proximal releasing ball 322 and a distal releasing ball 327. The implant 321 is located in a gap between sections of the delivery guide and are releasably attached to

the delivery guide by brackets or clips. The two balls are spaced in such a way that, in the variation shown in Figure $3D_1$, the distal ball 327 releases the distal end 331 of implant 321 and the proximal ball 322 then releases the proximal end 329 of implant 321 upon additional proximal movement of actuator 304. This sequence of events is shown in Figs. $3D_1$, $3D_2$, and $3D_3$. The implant 321, is shown to be completely released in Figure $3D_3$. In this variation, the implant 321 may be self-expanding, e.g., constructed of a superelastic alloy such as nitinol or another alloy having high elasticity, e.g., an appropriate stainless steel.

[0056] A structure similar to that shown in Figures $3D_1$, $3D_2$, and $3D_3$ may also be used to deploy an implant using fluid pressure as the releasing impetus.

[0057] Figures $3E_1$, $3E_2$, $3E_3$ and $3E_4$ show a hydraulic variation. Shown are the delivery guide 350, having a hollow lumen 352, a self-expanding implant 354 (shown variously as non-expanded (e.g., in a "first form") in Fig. $3E_1$, partially expanded in Fig. $3E_2$, and fully expanded in Figs. $3E_3$ and $3E_4$ (e.g., in a "second form")), and an actuator 356 with a sealing member 358 and a radio-opaque member 360.

[0058] The implant 354 (here shown to be a stent or the like) is held to the delivery guide 350 during delivery to the selected treatment site using distal brackets 364 and proximal brackets 362 or clips or the like. The proximal and distal brackets (364, 362) either include regions that cooperate with the fluid in lumen 352 to move upon application of increased pressure in that lumen 352 and release the implant 350 or move in concert with a separate pressure sensitive motion component.

[0059] Figure $3E_1$ shows the actuator 356 as the sealing member 358 approaches the various orifices or openings (proximal orifices 366 and distal orifices 368) communicating from the lumen 356 to the hydraulically or fluidly actuatable clips or retaining brackets (proximal brackets 362 and distal brackets 364).

[0060] Included in the description of this variation is a radio-opaque marker 360 on the actuator shaft 356 that allows the user to simply line up that actuator

marker 360 with a corresponding radio-opaque marker 370 or the delivery guide 350, increase the pressure in lumen 352 (via syringe, pump, etc.) and deploy the proximal end 371 of implant 354. The interior pressure raises or rotates the proximal clips or brackets 362 and moves them out of contact with the implant 354. Figure $3E_2$ shows the movement of the proximal end of implant 354 away from the delivery guide 350.

[0061] Figure $3E_3$ shows the axial movement of actuator 356 distally to a position where the sealing member 358 is positioned to actuate distal clips or brackets 364 and release the distal end of implant. Again, a radio-opaque marker 374 (perhaps with an additional identification band 376) has been depicted to show alignment of the radio-opaque marker or band 360 on the actuator shaft 356 prior to the increase in pressure for deployment.

[0062] Figure $3E_4$ shows final deployment at the implant 354 and proximal movement at the actuator 356, just prior to withdrawal of the delivery guide 350. The distal and proximal clips or brackets (362, 364) have relaxed to the surface of the delivery guide 350.

[0063] Alternatives to certain of the elements shown in the variation found in Figs. $3E_1$ to $3E_4$ is seen in Figs. $3F_1$ and $3F_2$ and includes, e.g., a cover element 380 to block or cover proximal orifices 366 during the pressurization of the distal orifices 368. The cover element 380 includes holes 382 to allow fluid flow past the cover element 380.

[0064] Fig. $3G_1$ shows a variation of the described system in which an implant or stent 371 is maintained in position on a hollow delivery guide 373 using spring clips 375 proximally and 377 distally. The spring clips hold the implant 371 in place during delivery and against guide member 373. An actuator 379 is used to remove the clips 375, 377 sequentially and to release each end of implant 371 in an independent fashion. Clips 375 and 377, after actuation or release, remain interior to the guide member 373 for later removal with that guide member. The system shown in Figures $3G_1$, $3G_2$ and $3G_3$ may be used to deliver a number of implants in a

sequential fashion. Since the retainer clips 375, 377 remain within the guide member 373 after delivery, the actuator 379 is able to slide past the site on guide member 373 where the clips 375, 377 resided prior to implant 371 deployment, down to and distally to a site on the guide member having another implant for subsequent delivery. Consequently, an arrangement such as this may be used to deploy, in a sequential fashion, a number of stents or the like without withdrawal of the guide member.

[0065] In the variation shown in Figs. $3G_1$, $3G_2$ and $3G_3$, the clips 375 and 377 are spring-biased to collapse within the lumen 381 of the guide member 373 once they are pushed into the respective slots 383 provided for such retraction. Such spring loaded clips retain the self expanding stent or implant 371 onto the face of guide member 373. Each of clips 375, 377 are shown in this variation to have hook members 387, 389 that engage the implant 371, often axially stretching the implant 371 and maintaining the delivery radius of the implant 371 as shown.

[0066] As shown in Fig. $3G_1$, actuator 379 is pushed distally along the outer surface of guide member 373 until it contacts the proximal end of clip 375. Further distal movement of actuator 379 urges clip 375 into lumen 381 thereby rotating horn 387 out of cooperating receptacle area in implant 371.

[0067] Fig. $3G_2$ shows the results of such movement after clip 375 has completed its springed closure within lumen 381. As shown in that Figure, the proximal end of implant 371 has expanded and yet the distal end of implant 371 remains closed and hooked to distal clip 377. This semi-open condition allows for some adjustment of the implant if needed. Fig. $3G_3$ shows the results of additional distal movement of actuator 379 until it contacts distal clip 377 (shown in Fig $3G_3$ in its collapsed form) and thereby allowing the distal end of implant 371 to self-expand into the chosen treatment site.

[0068] Fig. $3G_3$ shows that guide member 379 is free. Implant 371 is shown in its self expanded form no longer adjacent the central guide member 379. Actuator 379 is situated within implant 371 and is no longer in contact with proximal clip 375

nor distal clip 377. Actuator 379 is thus able to continue distally to another implant containing site positioned in a more distal site on the guide member 373.

[0069] The mechanical variation shown in Figs. $3G_1$, $3G_2$, $3G_3$ may be modified in such a way that the actuator is interior to the lumen of the guide member and deploys the implant upon distal movement of the actuator by providing an actuator with a slot or other "room-making" provisions in the actuator. The actuator and any retained clips would then be used to actuate the clips in the next more distal implant if so desired.

[0070] In yet a further variation, the system releases an implant (shown as a stent 404 in Fig. 4) attached to a delivery guide 400 by one or more attachment arms 402 positioned, e.g., at the implant proximal and distal ends, by sliding a tubular member 406, mounted co-axially on the delivery guide 400, distally over the delivery guide 400. The stent 404 is secured to the delivery guide 400 when the attachment arms 402 are in a radially expanded configuration (as illustrated in Figure 4). The tubular member 406 urges the attachment arms 402 into a compressed configuration as it slides distally over the delivery guide 400, in the direction of the arrow. When the attachment arms 402 are compressed by the tubular member 406, they are moved inward from the stent 404, toward the central axis of the delivery guide 400, thereby releasing the stent 404 from the delivery guide 400. Stent detachment occurs in a serial fashion as the tubular member 406 is moved distally, with detachment of the stent proximal end 408 occurring before detachment at the stent distal end 410. Consequently, if the stent position requires readjustment after detachment of the stent proximal end, the stent may be repositioned prior to detaching the stent distal end. In one variation, the tubular member is a balloon catheter.

[0071] The attachment arms 402 are generally made from the same materials as the delivery guide 400, e.g., stainless steel or nickel-titanium alloy, and will typically have a length, thickness, shape, and flexibility appropriate for its intended mechanism of release. The distal ends 412 of the attachment arms may be of any

design, so long as one or more of them, when in a radially expanded configuration, secures a portion of a stent to a delivery guide, and when in a compressed configuration, releases that same stent portion from the delivery guide.

[0072] The tubular member may be a thin-walled tube (e.g., approximately 0.005 cm (0.002 inches) in thickness) with an outside diameter ranging from about 0.025 cm to about 0.139 cm (0.010 inches to about 0.055 inches), more usually from about 0.025 cm to about 0.05 cm (0.010 inches to about 0.020 inches), and more usually still from about 0.025 cm to about 0.035 cm (0.010 inches to about 0.014 inches). Depending on such factors as degree of flexibility or durometer required, they may be made from various metals or metal alloys, including, but not limited to, stainless steel and nickel-titanium alloy, or from various polymers, such as polyvinyl chloride, polyethylene, polyethylene terephthalate, and polyurethane.

[0073] Figures 5A, 5B, and 5C show a variation of the described delivery system 500 in which a member of electrolytic delivery joints are used to deploy an implant 502, such as a stent.

[0074] The electrolytic delivery joints shown here (e.g., 504 in Figure 5C) are well known as controllable delivery joints for placement of vaso-occlusive coils. One such commercially available device using an electrolytically detachable joint is sold by Target Therapeutics, a subsidiary of Boston Scientific Corp., as the Guglielmi Detachable Coil (or "GDC"). Numerous patents to Dr. Guglielmi describe the theory of its use.

[0075] In essence, the electrolytically erodible joint is a section of an electrical circuit that is not insulated and is of a metallic material that does not form insulating oxides when exposed to an aqueous environment (e.g., aluminum and tantalum) and is sufficiently "non-noble" that is will either electrolytically erode by ionic dissolution into an anatomical fluid or, perhaps, electrochemically erode by forming readily soluble oxides or salts.

[0076] The erodible joint 504 shown in Figure 5C is a bare metal of a size, diameter, etc. that erodes away when a current is applied to insulated wire 506. The current flow is from a power supply through insulated wire 506, bare joint 504, into the ionic anatomical fluid surrounding the site to be treated, and back to a return electrode situated perhaps on the patient's skin and then back to the power supply. The current flows through the circuit so long as the joint 504 exists.

[0077] With that background, Figure 5A shows a device having several joints (504, 508, 510, 512) that each may be independently severed to controllably deploy the implant 502. Implant 502 is shown having coils (514, 516) that are terminated at each end by an erodible joint and that, prior to the severing of a joint, hold this implant 502 to the surface of the delivery member 520. The implant 500 is self-expanding, once released. The wires forming the two coils in this variation slide within the implant or "uncoil" and thereby allow the implant body itself to expand. The coils may comprise (if electrically connected to the erodible joint) a metal that is higher in the Mendelev Electromotive Series than is the composition at the electrolytic joint or the coils may comprise a polymer that may be bio-erodible or not.

[0078] In any case, a suitable way to assure that the coils (514, 516) maintain the low profile of the implant 502 during delivery is via the placement of the various conductive wires (506, 516, 518, 520) through the adjacent holes (524, 526, 528) and fill the holes with e.g., an epoxy to hold all in place. Independently causing current to flow through each of the joints will release the implant in the region of the released joint Once all joints are eroded, the implant is released.

[0079] Although release from proximal and distal ends of the tubular form of the implants has been described, detachment from a delivery guide is not so limited. In another variation, the stent is attached to the delivery guide at one or more positions along the length of the stent, in addition to attachment at the proximal and distal implant ends. Once the distal stent end is released, the additional attachments may be independently released until detachment at the proximal implant end releases

the implant entirely from the delivery guide. Serial release may provide better control of positioning in tubular organs.

[0080] Figs. 5D and 5E show in more detail, the components of an electrolytic joint (as may be found in Figs 5A, 5B and 5C) and another electrically actuated joint using a meltable or softenable or polymerically sizable joint.

[0081] Fig. 5D shows the insulated wire 524 with insulation 523 and conductor 525. The electrolytic joint 504 is also shown. In this variation, the wire 524 is shown to be secured into the delivery guide wall 520 by, e.g., an epoxy 527, an alternative or cooperative band or component 529 holding the wire 524 to the surface of guide member 520 is also shown. After erodable joint 504 is eroded, the implant of 502 expands and leaves the securement band 529 on the delivery guide 520.

[0082] Fig. 5E shows a similar variation but the joint comprises a thermoplastic adhesive or shape changing polymer 531 situated on the end of wire 525 and within a cup or other receptacle 533. The adhesive is of the type that changes form or viscosity upon application of current to the joint. In this variation, the thermoplastic is rendered conductive, but resistive, by introduction of material such as carbon black into the polymeric adhesive. As soon as the polymer changes its shape, form, or phase, the implant expands to the desired form about the central guide member 520 again, the wire may be held in place with an adhesive 527 if so desired.

[0083] Although the figures show wires and other remnants of the joints remaining exterior to the central guide member 520 and the others shown and described here, it is desirable that these not be situated in such a way that they will harm the tissues into which they are placed.

Delivery Method

[0084] The implant delivery devices described herewith may include multiple implants on a single delivery guide or may be used in conjunction with other instruments, as seen appropriate, to treat the target site. In general, the tubular organ

of interest is percutaneously accessed, but the method of accessing will usually be dependent on the anatomy of the organ, medical condition being treated, health status of the subject, and the like. Consequently, access by a laparoscopic or open procedure may also be obtained.

[0085] Figures 6A-6D show the general method of deploying a stent using my described system. After obtaining access to the tubular organ of interest 600 (blood vessel in Figure 6A), a delivery guide 602 is placed through the selected area of stenosis 604 at the target site. A balloon catheter 606 is then advanced over the delivery guide 602, and balloon angioplasty performed to dilate the area of stenosis 604 (Figure 6B). The balloon catheter 606 is then retracted proximally and the delivery guide 602 exchanged for a stent delivery device 608 (Figure 6C). Appropriate placement of the stent is guided by radioopaque markers 616 on the delivery guide 612. The distal end 610 of the stent is then released from the delivery guide 612. At this point, stent position may again be checked by verifying the location of the radioopaque markers. The proximal stent end 614 is then released from the delivery guide 612.

[0086] If desired, an embolic filter may be used during stent deployment to filter any debris generated during the procedure. The filter will usually be attached to the delivery guide such that it filters debris distal to the stent, but may also be attached to the delivery guide proximal to the stent, or both distal and proximal to the stent. The filter may be of any design, as long as it does not affect the substantially atraumatic, low profile, and controlled release characteristics of the stent delivery device. Typically, the filter is basket-shaped, and made from a shape-memory material, e.g., an alloy of titanium and nickel. The filter will usually be contained within the balloon catheter lumen, and deployed to its pre-designed shape once the balloon catheter is removed. Following placement of the stent, the balloon catheter may be advanced over the delivery guide to enclose the filter with any accumulated

debris. The balloon catheter, filter, and delivery guide may then be removed from the body.

Applications

[0087] The implant delivery system may be used in mammalian subjects, preferably humans. Mammals include, but are not limited to, primates, farm animals, sport animals, cats, dogs, rabbits, mice, and rats.

[0088] The system may be employed for implant delivery into lumens of tubular organs including, but not limited to, blood vessels (including intracranial vessels, large vessels, peripheral vessels, aneurysms, arteriovenous malformations, arteriovenous fistulas), ureters, bile ducts, fallopian tubes, cardiac chambers, ducts such as bile ducts and mammary ducts, large and small airways, and hollow organs, e.g., stomach, intestines, and bladder. The system may also be employed for implant delivery into solid organs or tissues including, but not limited to, skin, muscle, fat, brain, liver, kidneys, spleen, and benign and malignant tumors. Preferably, the implant is delivered to a target site in a blood vessel lumen.

[0089] Clinically, the system may generally be used to treat stenosis of various tubular organs, arising from such etiologies as atherosclerosis, autoimmune conditions, scarring, or exterior compression, e.g., as may be seen with a neoplastic process. The system may also be used to treat medical conditions in which luminal occlusion is desired, e.g., to treat aneurysms, arteriovenous fistulas, and arteriovenous malformations. Furthermore, the system may be employed to deliver implants into such areas as joint spaces, spinal discs, and the intraperitoneal or extraperitoneal spaces.

* * *

All publications, patents, and patent applications cited herein are hereby incorporated by reference in their entirety for all purposes to the same extent

as if each individual publication, patent, or patent application were specifically and individually indicated to be so incorporated by reference. Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit and scope of the appended claims.

CLAIMS

1. An implant delivery device comprising:

a.) a noninflatable, elongate delivery guide member having a distal end, said guide member configured to direct at least one implant having an exterior and interior surface to an anatomical treatment site by manipulation by a user,

b.) the at least one implant having a delivery diameter prior to release of the at least one implant, the implant located proximally of the distal end of the delivery guide member prior to release, and

c.) at least one releasable joint configured to maintain at least a section of the at least one implant at the delivery diameter until release of the at least one releasable joint.

2. The device of claim 1 wherein the at least one implant comprises exactly one implant.

3. The device of claim 1 wherein the at least one implant comprises more than one implant.

4. The device of claim 1 wherein the delivery guide member comprises a distal guide section and a proximal guide section and a gap between the distal guide section and the proximal guide section and the at least one implant is located between the distal guide section and the proximal guide section.

5. The device of claim 1 wherein the delivery guide member has a diameter distally on the proximal guide section and a diameter proximally on the distal guide

section, and wherein the at least one implant delivery diameter is substantially equal to the delivery guide member diameter.

6. The device of claim 1 wherein the delivery guide member comprises a tubular member having a lumen.

7. The device of claim 6 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon axial movement within the delivery guide member.

8. The device of claim 7 wherein the actuator is configured to sequentially release more than one releasable joint upon axial movement within the delivery guide member.

9. The device of claim 7 wherein the actuator is configured to simultaneously release more than one releasable joint upon axial movement within the delivery guide member.

10. The device of claim 6 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon rotational movement within the delivery guide member.

11. The device of claim 6 wherein the at least one releasable joint is configured to release upon application of fluid pressure in the delivery guide member lumen and further comprising a fluid director slidably located at least partially within the delivery guide member lumen and configured to direct fluid to and to release that selected at least one releasable joint.

12. The device of claim 11 wherein the fluid director is configured to sequentially release more than one releasable joint upon application of fluid pressure in the delivery guide member lumen.

13. The device of claim 6 wherein the at least one releasable joint is configured to release upon application of a suitable DC current to the at least one releasable joint and further comprising an electrical conductor located at least partially within the delivery guide member lumen to supply said suitable DC current to and to thereby release at least one releasable joint.

14. The device of claim 13 wherein the at least one releasable joints and electrical conductors are configured to sequentially release more than one releasable joint.

15. The device of claim 13 wherein the at least one releasable joints and electrical conductors are configured to simultaneously release more than one releasable joint.

16. The device of claim 1 wherein the implant is a stent.

17. The device of claim 16 wherein the stent is unsheathed.

18. The device of claim 1 wherein the implant is an occlusive coil.

19. The device of claim 1 wherein the implant further comprises a therapeutic agent.

20. The device of claim 19 wherein the therapeutic agent is selected from the group consisting of antibiotics, anticoagulants, antifungal agents, anti-inflammatory agents, antineoplastic agents, antithrombotic agents, endothelialization promoting

agents, free radical scavengers, immunosuppressive agents, thrombolytic agents, and combinations thereof.

21. The device of claim 1 wherein the delivery guide further comprises a radioopaque marker.

22. The device of claim 1 wherein the implant exterior surface is smooth after deployment.

23. The device of claim 1 wherein the implant interior surface is smooth after deployment.

24. A guidewire-less implant delivery system comprising:

a.) a noninflatable, elongate delivery guide member having a proximal end and a distal end, said guide member configured to direct at least one implant having an exterior and interior surface to an anatomical treatment site by manipulation by a user,

b.) the at least one implant having a delivery diameter prior to release of the at least one implant and located proximally of the distal end of the delivery guide member prior to release, and

c.) at least one releasable joint configured to maintain at least a section of the at least one implant at the delivery diameter until release of the at least one releasable joint.

25. The system of claim 24 wherein the guide member is closed at its distal end.

26. The system of claim 24 wherein the delivery guide member has a diameter distally and proximally of the at least one implant that is substantially equal to the at least one implant delivery diameter.

27. The system of claim 24 wherein the delivery guide member has no passageway from its proximal to its distal end.

28. The system of claim 24 further comprising an actuator for releasing the at least one releasable joint, and wherein the delivery guide member has only a single passageway from its proximal to its distal end, that passageway contains the actuator, and that actuator does not extend beyond the distal end of the delivery guide member.

29. The system of claim 28 wherein the actuator for releasing the at least one releasable joint is affixed to the distal end of the delivery guide member.

30. The system of claim 24 wherein the at least one implant comprises exactly one implant.

31. The system of claim 24 wherein the at least one implant comprises more than one implant.

32. The system of claim 24 wherein the delivery guide member comprises a distal guide section and a proximal guide section and a gap between the distal guide section and the proximal guide section and the at least one implant is located between the distal guide section and the proximal guide section.

33. The system of claim 24 wherein the delivery guide member has a diameter distally on the proximal guide section and a diameter proximally on the distal guide section, and wherein the at least one implant delivery diameter is substantially equal to the delivery guide member diameter.

34. The system of claim 24 wherein the delivery guide member comprises a tubular member having a lumen.

35. The system of claim 34 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon axial movement within the delivery guide member.

36. The system of claim 35 wherein the actuator is configured to sequentially release more than one releasable joint upon axial movement within the delivery guide member.

37. The system of claim 35 wherein the actuator is configured to simultaneously release more than one releasable joint upon axial movement within the delivery guide member.

38. The system of claim 34 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon rotational movement within the delivery guide member.

39. The system of claim 34 wherein the at least one releasable joint is configured to release upon application of fluid pressure in the delivery guide member lumen and further comprising a fluid director slidably located at least partially within the delivery guide member lumen and configured to direct fluid to and to release that selected at least one releasable joint.

40. The system of claim 39 wherein the fluid director is configured to sequentially release more than one releasable joint upon application of fluid pressure in the delivery guide member lumen.

41. The system of claim 34 wherein the at least one releasable joint is configured to release upon application of a suitable DC current to the at least one releasable joint and further comprising an electrical conductor located at least partially within the delivery guide member lumen to supply said suitable DC current to and to thereby release at least one releasable joint.

42. The system of claim 41 wherein the at least one releasable joints and electrical conductors are configured to sequentially release more than one releasable joint.

43. The system of claim 41 wherein the at least one releasable joints and electrical conductors are configured to simultaneously release more than one releasable joint.

44. The system of claim 24 wherein the implant is a stent.

45. The system of claim 44 wherein the stent is unsheathed.

46. The system of claim 24 wherein the implant is an occlusive coil.

47. The system of claim 24 wherein the implant further comprises a therapeutic agent.

48. The system of claim 47 wherein the therapeutic agent is selected from the group consisting of antibiotics, anticoagulants, antifungal agents, anti-inflammatory agents, antineoplastic agents, antithrombotic agents, endothelialization promoting agents, free radical scavengers, immunosuppressive agents, thrombolytic agents, and combinations thereof.

49. The system of claim 24 wherein the delivery guide further comprises a radioopaque marker.

50. A guidewire-less implant delivery system having flexibility and remote directability comprising:

a.) a noninflatable, elongate delivery guide member having a proximal and a distal end, said guide member configured to direct at least one implant having an exterior and interior surface to an anatomical treatment site by manipulation by a user,

b.) the at least one implant having a delivery diameter prior to release of the at least one implant and located proximally of the distal end of the delivery guide member prior to release,

c.) at least one releasable joint configured to maintain at least a section of the at least one implant at the delivery diameter until release of the at least one releasable joint, and

wherein the remote directability is such that a user may direct the distal end of the guide member into and introduce the at least one implant into a coronary artery solely by manipulation of the delivery guide member from its proximal end.

51. The system of claim 50 wherein the guide member is closed at its distal end.

52. The system of claim 50 wherein the delivery guide member has a diameter distally and proximally of the at least one implant that is substantially equal to the at least one implant delivery diameter.

53. The system of claim 50 wherein the delivery guide member has no passageway from its proximal to its distal end.

54. The system of claim 50 further comprising an actuator for releasing the at least one releasable joint, and wherein the delivery guide member has only a single

passageway from its proximal to its distal end, that passageway contains the actuator, and that actuator does not extend beyond the distal end of the delivery guide member.

55. The system of claim 54 wherein the actuator for releasing the at least one releasable joint is affixed to the distal end of the delivery guide member.

56. The system of claim 50 wherein the at least one implant comprises exactly one implant.

57. The system of claim 50 wherein the at least one implant comprises more than one implant.

58. The system of claim 50 wherein the delivery guide member comprises a distal guide section and a proximal guide section and a gap between the distal guide section and the proximal guide section and the at least one implant is located between the distal guide section and the proximal guide section.

59. The system of claim 50 wherein the delivery guide member has a diameter distally on the proximal guide section and a diameter proximally on the distal guide section, and wherein the at least one implant delivery diameter is substantially equal to the delivery guide member diameter.

60. The system of claim 50 wherein the delivery guide member comprises a tubular member having a lumen.

61. The system of claim 60 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon axial movement within the delivery guide member.

62. The system of claim 61 wherein the actuator is configured to sequentially release more than one releasable joint upon axial movement within the delivery guide member.

63. The system of claim 61 wherein the actuator is configured to simultaneously release more than one releasable joint upon axial movement within the delivery guide member.

64. The system of claim 60 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon rotational movement within the delivery guide member.

65. The system of claim 60 wherein the at least one releasable joint is configured to release upon application of fluid pressure in the delivery guide member lumen and further comprising a fluid director slidably located at least partially within the delivery guide member lumen and configured to direct fluid to and to release that selected at least one releasable joint.

66. The system of claim 65 wherein the fluid director is configured to sequentially release more than one releasable joint upon application of fluid pressure in the delivery guide member lumen.

67. The system of claim 60 wherein the at least one releasable joint is configured to release upon application of a suitable DC current to the at least one releasable joint and further comprising an electrical conductor located at least partially within the delivery guide member lumen to supply said suitable DC current to and to thereby release at least one releasable joint.

68. The system of claim 67 wherein the at least one releasable joints and electrical conductors are configured to sequentially release more than one releasable joint.

69. The system of claim 67 wherein the at least one releasable joints and electrical conductors are configured to simultaneously release more than one releasable joint.

70. The system of claim 50 wherein the implant is a stent.

71. The system of claim 70 wherein the stent is unsheathed.

72. The system of claim 50 wherein the implant is an occlusive coil.

73. The system of claim 50 wherein the implant further comprises a therapeutic agent.

74. The system of claim 73 wherein the therapeutic agent is selected from the group consisting of antibiotics, anticoagulants, antifungal agents, anti-inflammatory agents, antineoplastic agents, antithrombotic agents, endothelialization promoting agents, free radical scavengers, immunosuppressive agents, thrombolytic agents, and combinations thereof.

75. The system of claim 50 wherein the delivery guide further comprises a radioopaque marker.

76. A system for delivering an implant to a target site in a tubular organ comprising:

a) the device of any one of claims 1-23; and

b) a balloon catheter.

77. The system of claim 76 further comprising an embolic filter.

78. The system of claim 77 wherein the embolic filter is attached to the proximal end of the delivery guide.

79. The system of claim 76 wherein the implant is a stent.

80. The system of claim 76 wherein the implant is an occlusive coil.

81. A method for delivering an implant in a subject comprising:

a) accessing a body region;

b) advancing the device of any one of claims 1-23 to a target site in the body region; and

c) releasing the implant at the target site.

82. The method of claim 81 further comprising the step of deploying at least one embolic filter.

83. The method of claim 81 wherein the step of releasing comprises detaching the distal end of the implant from the delivery guide before detaching the proximal end of the implant from the delivery guide.

84. The method of claim 81 wherein the step of releasing comprises a mechanical detachment process.

85. The method of claim 81 wherein the step of releasing comprises a hydraulic detachment process.

86. The method of claim 81 wherein the step of releasing comprises an electrolytic detachment process.

87. The method of claim 81 wherein the body region is a tubular or hollow organ.

88. The method of claim 87 wherein the tubular or hollow organ is selected from the group consisting of blood vessels, arteriovenous malformations, aneurysms, arteriovenous fistulas, cardiac chambers, bile ducts, mammary ducts, fallopian tubes, ureters, large and small airways, stomach, intestines, and bladder.

89. The method of claim 81 wherein the body region is a blood vessel.

90. The method of claim 81 wherein the implant is a stent.

91. The method of claim 81 wherein the implant is an occlusive coil.

92. The method of claim 81 wherein the target site comprises an aneurysm.

93. The method of claim 81 wherein the subject is human.

94. The method of claim 81 wherein the step of accessing is percutaneous.

In the Claims

Please amend the claims as follows:

1. - 21. (Cancelled, without prejudice)

22. (Currently Amended) The ~~device~~ system of claim ~~1~~ 24 wherein the implant exterior surface is smooth after deployment.

23. (Currently Amended) The ~~device~~ system of claim ~~1~~ 24 wherein the implant interior surface is smooth after deployment.

24. (Currently Amended) A ~~guidewire less~~ implant delivery system comprising:

~~a.) a noninflatable,~~ an elongate delivery guide member having a proximal end and a distal end, ~~said~~ the delivery guide member configured to direct at least one implant having an exterior and interior surface to an anatomical treatment site by manipulation by a user,

~~b.)~~ the at least one implant having a delivery diameter prior to release of the at least one implant and located proximally of the distal end of the delivery guide member prior to release, ~~and~~

~~c.)~~ at least one releasable joint configured to maintain at least a section of the at least one implant at the delivery diameter until release of the at least one releasable joint, and

a balloon catheter having a lumen, the delivery guide member being positioned within the lumen.

25. (Currently Amended) The system of claim 24 wherein the delivery guide member is closed at its distal end.

26. (Currently Amended) The system of claim 24 wherein the delivery guide member has a diameter distally and proximally of the at least one implant that is substantially equal to the at least one implant delivery diameter, whereby a substantially atraumatic implant delivery system is provided.

27. (Original) The system of claim 24 wherein the delivery guide member has no passageway from its proximal to its distal end.

28. (Original) The system of claim 24 further comprising an actuator for releasing the at least one

releasable joint, and wherein the delivery guide member has only a single passageway from its proximal to its distal end, that passageway contains the actuator, and that actuator does not extend beyond the distal end of the delivery guide member.

29. (Currently Amended) The system of claim 28 wherein the actuator for releasing the ~~at least one~~ releasable joints is affixed to the distal end of the delivery guide member.

30. (Original) The system of claim 24 wherein the at least one implant comprises exactly one implant.

31. (Original) The system of claim 24 wherein the at least one implant comprises more than one implant.

32. (Original) The system of claim 24 wherein the delivery guide member comprises a distal guide section and a proximal guide section and a gap between the distal guide section and the proximal guide section and the at least one implant is located between the distal guide section and the proximal guide section.

33. (Currently Amended) The system of claim 24 wherein the delivery guide member has a diameter distally ~~on the proximal guide section and a diameter~~ and proximally of the ~~on the distal guide section, and wherein the~~ at least one implant, and the at least one implant delivery diameter ~~is substantially equal to the delivery guide member diameter~~ and delivery guide member diameters are about 0.010 inches to about 0.020 inches, whereby a low-profile delivery system is provided

34. (Currently Amended) The system of claim 24 wherein the delivery guide member ~~comprises a~~ is tubular ~~member~~ in form, having a lumen therein.

35. (Original) The system of claim 34 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon axial movement within the delivery guide member.

36. (Original) The system of claim 35 wherein the actuator is configured to sequentially release

more than one releasable joint upon axial movement within the delivery guide member.

37. (Original) The system of claim 35 wherein the actuator is configured to simultaneously release more than one releasable joint upon axial movement within the delivery guide member.

38. (Original) The system of claim 34 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon rotational movement within the delivery guide member.

39. (Currently Amended) The system of claim 34 wherein ~~the~~ at least one releasable joint is configured to release upon application of fluid pressure in the delivery guide member lumen and further comprising a fluid director slidably located at least partially within the delivery guide member lumen and configured to direct fluid to and to release that selected at least one releasable joint.

40. (Original) The system of claim 39 wherein the fluid director is configured to sequentially release more than one releasable joint upon application of fluid pressure in the delivery guide member lumen.

41. (Original) The system of claim 34 wherein the at least one releasable joint is configured to release upon application of a suitable DC current to the at least one releasable joint and further comprising an electrical conductor located at least partially within the delivery guide member

42. (Original) The system of claim 41 wherein the at least one releasable joints and electrical conductors are configured to sequentially release more than one releasable joint.

43. (Original) The system of claim 41 wherein the at least one releasable joints and electrical conductors are configured to simultaneously release more than one releasable joint.

44. (Original) The system of claim 24 wherein the implant is a stent.

45. (Original) The system of claim 44 wherein the stent is unsheathed.

46. (Cancelled, without prejudice)

47. (Original) The system of claim 24 wherein the implant further comprises a therapeutic agent.

48. (Original) The system of claim 47 wherein the therapeutic agent is selected from the group consisting of antibiotics, anticoagulants, antifungal agents, anti-inflammatory agents, antineoplastic agents, antithrombotic agents, endothelialization promoting agents, free radical scavengers, immunosuppressive agents, thrombolytic agents, and combinations thereof.

49. (Currently Amended) The system of claim 24 wherein the delivery guide member further comprises a radioopaque marker.

50. (Currently Amended) ~~A guidewire less implant delivery system~~ The system of claim 24 having flexibility and remote directability, ~~comprising:~~

~~a.) a noninflatable, elongate delivery guide member having a proximal and a distal end, said guide member configured to direct at least one implant having an exterior and interior surface to an anatomical treatment site by manipulation by a user,~~

~~b.) the at least one implant having a delivery diameter prior to release of the at least one implant and located proximally of the distal end of the delivery guide member prior to release,~~

~~c.) at least one releasable joint configured to maintain at least a section of the at least one implant at the delivery diameter until release of the at least one releasable joint, and~~

wherein the remote directability is such that a user may direct the distal end of the delivery guide member into and introduce the at least one implant into a coronary artery solely by manipulation of the delivery guide member from its proximal end.

51. (Currently Amended) The system of claim ~~50~~ 24 wherein the ~~guide member is closed at its distal end~~ the system is guidewireless.

52. - 75. (Cancelled, without prejudice)

76. (Currently Amended) A system for ~~delivering an implant to~~ treating a target site in a tubular organ, the system consisting essentially of ~~comprising~~:

~~a) the device of any one of claims 1-23~~ an elongate delivery guide member having a proximal

end and a distal end, the delivery guide member configured to direct at least one implant having an exterior and interior surface to an anatomical treatment site by manipulation by a user, the at least one implant having a delivery diameter prior to release of the at least one implant and located proximally of the distal end of the delivery guide member prior to release, and at least one releasable joint configured to maintain at least a section of the at least one implant at the delivery diameter until release of the at least one releasable joint; and

~~b)~~ a balloon catheter,

wherein the delivery guide member is adapted for receipt within a lumen of the balloon catheter.

77. (Currently Amended) ~~The~~ A system consisting essentially of the system of claim 76 ~~further comprising an embolic filter~~ and a guidewire, wherein the guidewire is adapted for receipt within a lumen of the balloon catheter.

78. (Currently Amended) ~~The system of claim 77~~ A system consisting essentially of the system of claim 76 and an embolic filter, wherein the embolic filter is attached to the proximal end of the delivery guide.

79. (Original) The system of claim 76 wherein the implant is a stent.

80. (Cancelled, without prejudice).

81. (Currently Amended) A method for ~~delivering an implant in~~ treating a target site in a tubular organ of a subject, the method comprising:

~~a)~~ accessing a body region;

~~b) advancing the device of any one of claims 1-23~~ moving an delivery guide member carrying an implant to a target site in the body region through a balloon catheter lumen;

dilating an area of stenosis at the target site with the balloon catheter; and

~~c)~~ releasing the implant at the target site.

82. (Currently Amended) The method of claim 81 further comprising ~~the step of~~ deploying at least one embolic filter.

83. (Currently Amended) The method of claim 81 wherein the ~~step of~~ releasing comprises ~~detaching the~~ releasing a distal end of the implant from the delivery guide member before ~~detaching the~~ releasing a proximal end of the implant from the delivery guide member.

84. (Currently Amended) The method of claim 81 wherein the ~~step of~~ releasing comprises a mechanical detachment process.

85. (Currently Amended) The method of claim 81 wherein the ~~step of~~ releasing comprises a hydraulic detachment process.

86. (Currently Amended) The method of claim 81 wherein the ~~step of~~ releasing comprises an electrolytic detachment process.

87. (Original) The method of claim 81 wherein the body region is a tubular or hollow organ.

88. (Original) The method of claim 87 wherein the tubular or hollow organ is selected from the group consisting of blood vessels, arteriovenous malformations, aneurysms, arteriovenous fistulas, cardiac chambers, bile ducts, mammary ducts, fallopian tubes, ureters, large and small airways, stomach, intestines, and bladder.

89. (Original) The method of claim 81 wherein the body region is a blood vessel.

90. (Original) The method of claim 81 wherein the implant is a stent.

91., 92. (Cancelled, without prejudice)

93. (Original) The method of claim 81 wherein the subject is human.

94. (Currently Amended) The method of claim 81 wherein the ~~step of~~ accessing is performed percutaneously.

95. (New) The method of claim 81 wherein the stent implant delivery system is selected from those

described in any of claims 22-46, 47-51 or 76-79.

96. (New) The method of claim 81 further comprising:
advancing a guidewire to the treatment site;
advancing the balloon catheter over the guidewire to the treatment site; and
exchanging the guidewire for the delivery guide member.

97. (New) The method of claim 81 further comprising:
retracting the balloon catheter so a distal end of the catheter is adjacent the treatment site before the releasing of the implant.

98. The method of claim 81 further comprising:
advancing the delivery guide member beyond a distal end of the balloon catheter.

99. (New) The method of claim 98 where after the advancing of the delivery guide member, the method further comprises retracting the balloon catheter so a distal end of the catheter is adjacent the treatment site before the releasing of the implant.

100. (New) The system of claim 24 wherein the delivery guide member is noninflatable.

101. (New) The system of claim 25, wherein an atraumatic tip provides the end closure

ABSTRACT OF THE DISCLOSURE

The invention provides an atraumatic, low profile device for the delivery of one or more implants into tubular organs or open regions of the body. The implant delivery device may simultaneously or independently release portions of the implant, e.g., the proximal and distal ends of the implant. This independent release feature allows better implant positioning at the target site. Upon deployment, the implants may be placed at the target site without a sheath.

PTO/SB/01a (10-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	*BALLOON CATHETER LUMEN BASED STENT DELIVERY SYSTEMS*

As the below named inventor(s), I/we declare that:

This declaration is directed to:

☒ The attached application, or
☐ Application No. _ filed on ,

☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application, if applicable; and.

All statements made herein of my/our own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

As a named inventor I hereby appoint Practitioners at Customer Number 24353 as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith

FULL NAME OF INVENTOR(S)

Inventor one: NIKOLCHEV, JULIAN

Signature: _____ Citizen of: USA

Inventor two:

Signature: _____ Citizen of: _____

Inventor three:

Signature: _____ Citizen of: _____

Inventor four

Signature: _____ Citizen of: _____

☐ Additional Inventors are being named on additional form(s) attached hereto.

FIGURE 1A

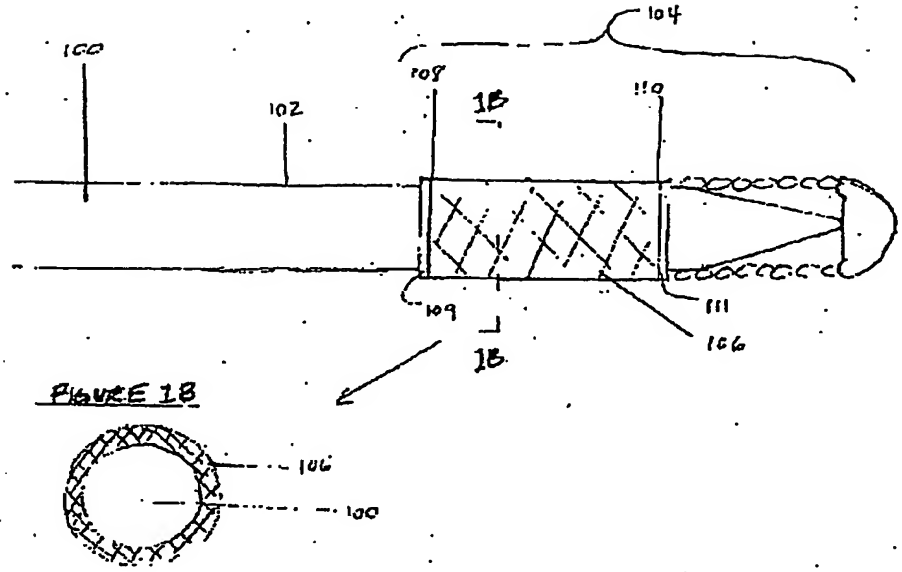


FIGURE 2

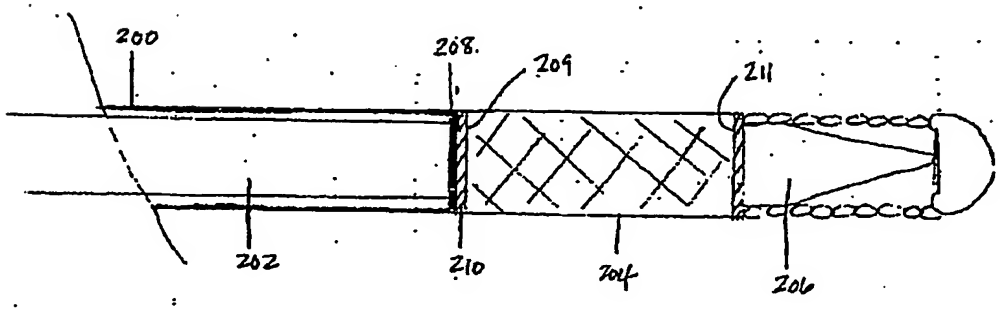


FIGURE 3A

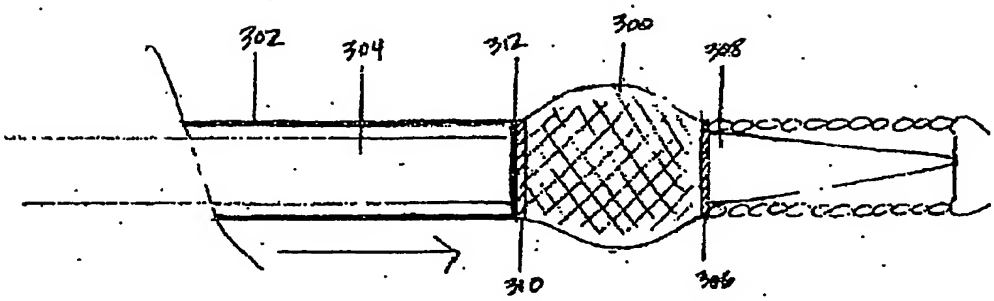


FIGURE 3B

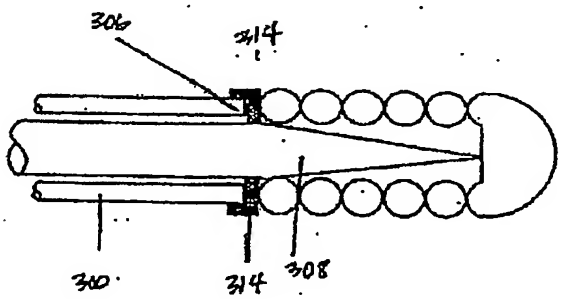


FIGURE 3C

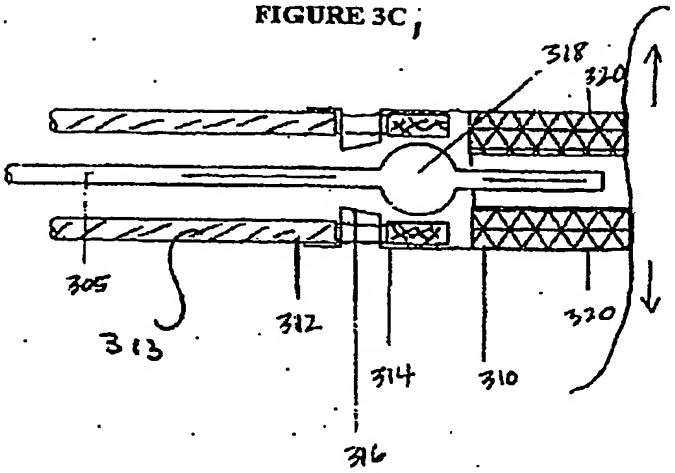
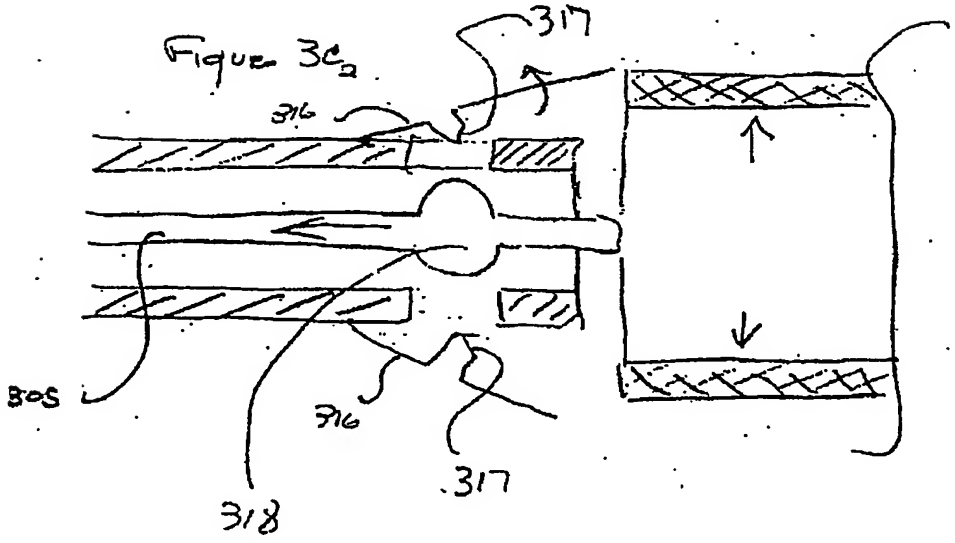


Figure 3C2



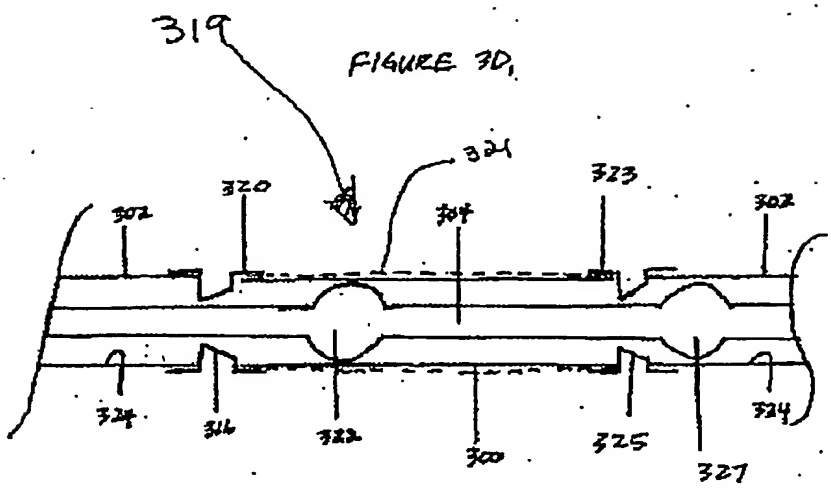


FIGURE 3D

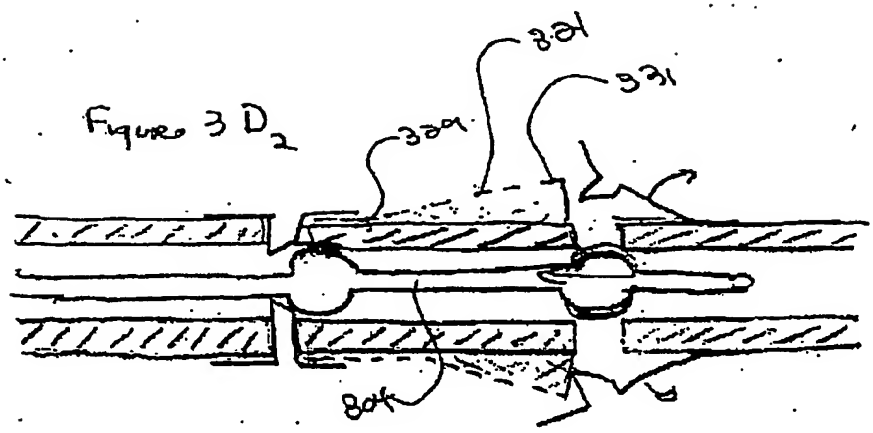


Figure 3 D_2

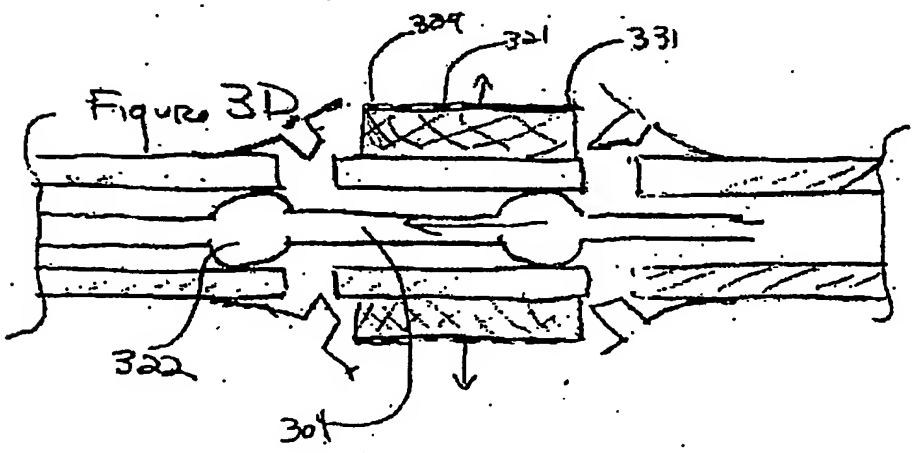


Figure 3D

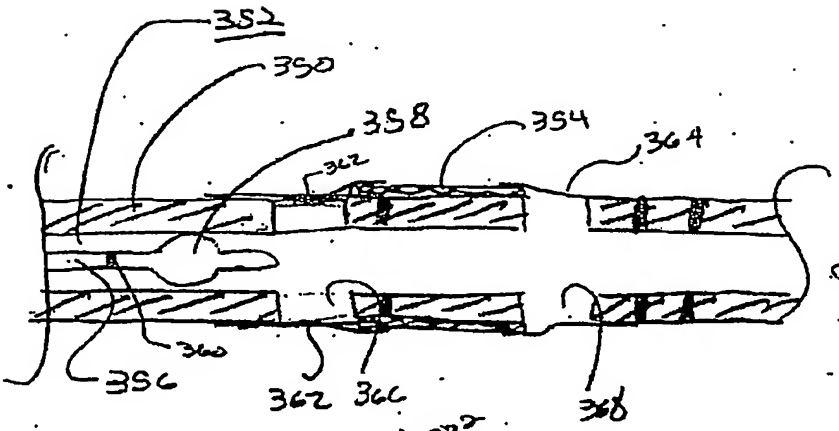


Figure 3E.

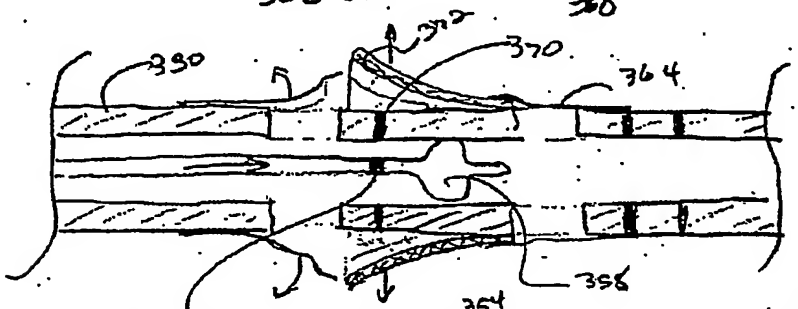


Figure 3E2

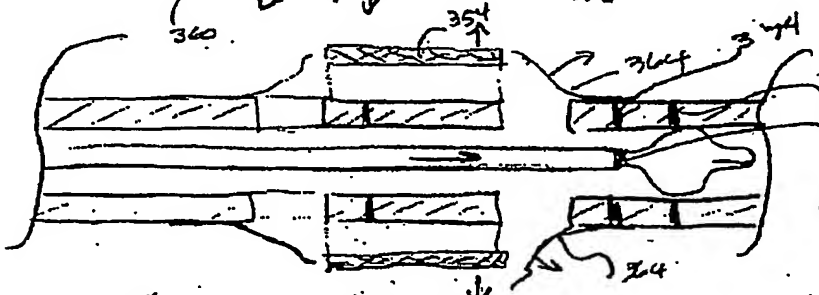


Figure 3E5

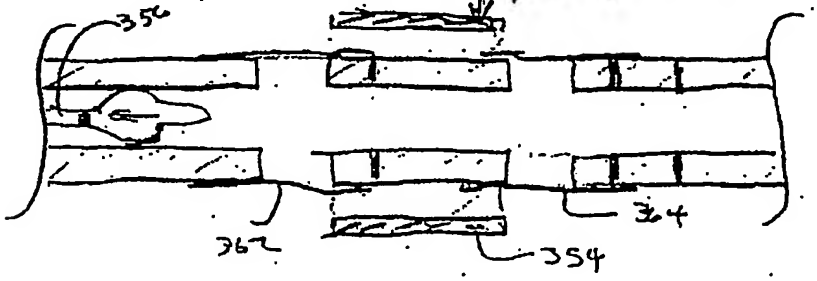


Figure 3E4

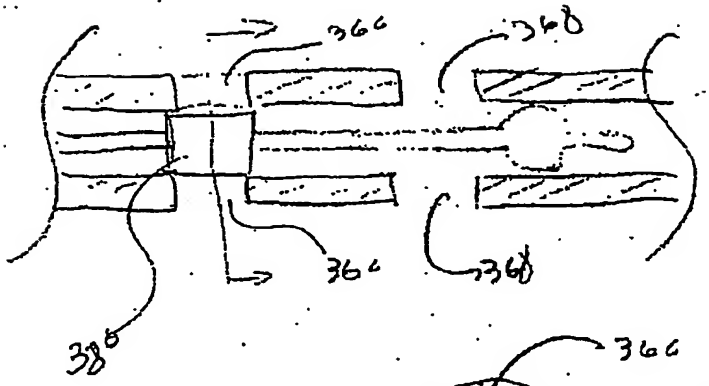


Fig 3F1

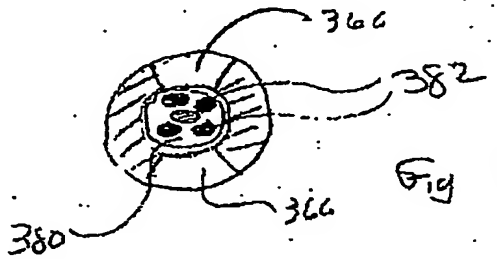


Fig 3F2

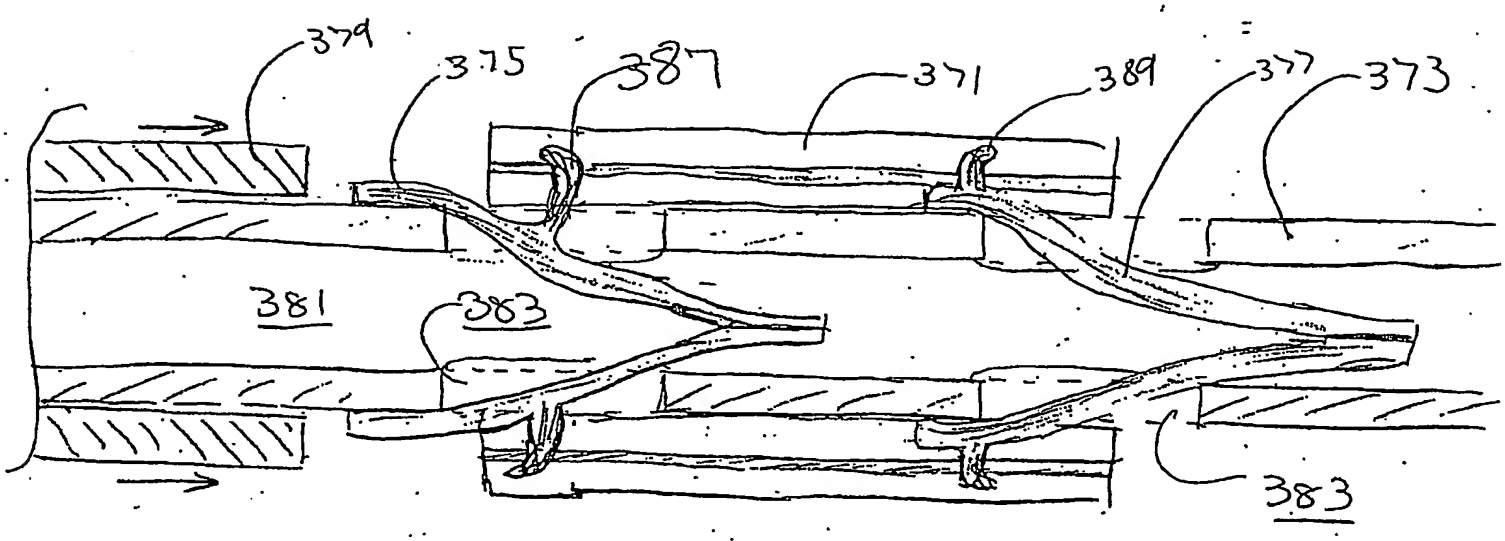


Figure 3G1

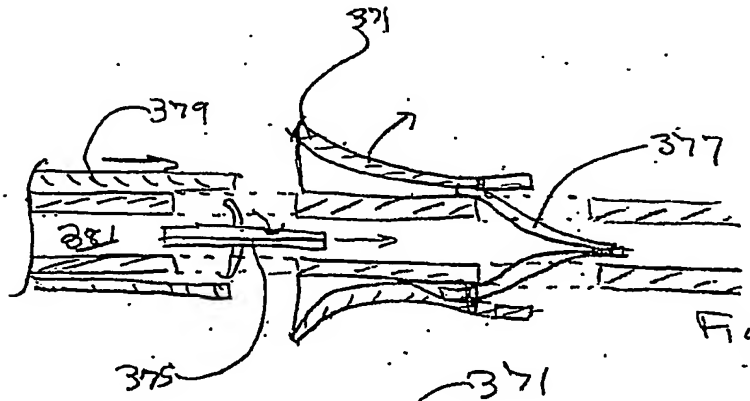


Figure 3G2

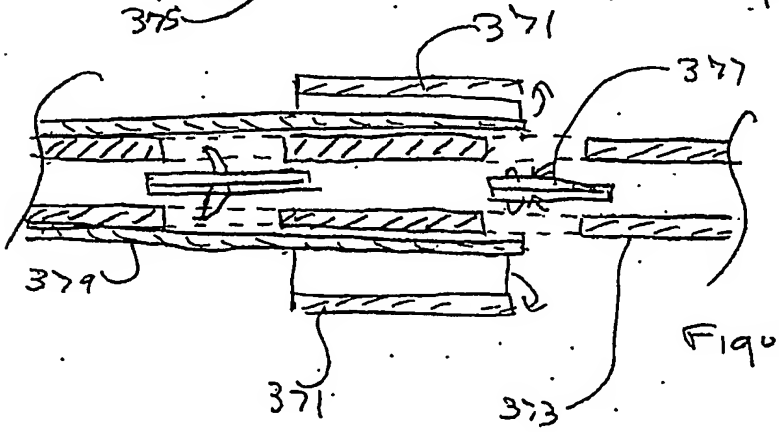
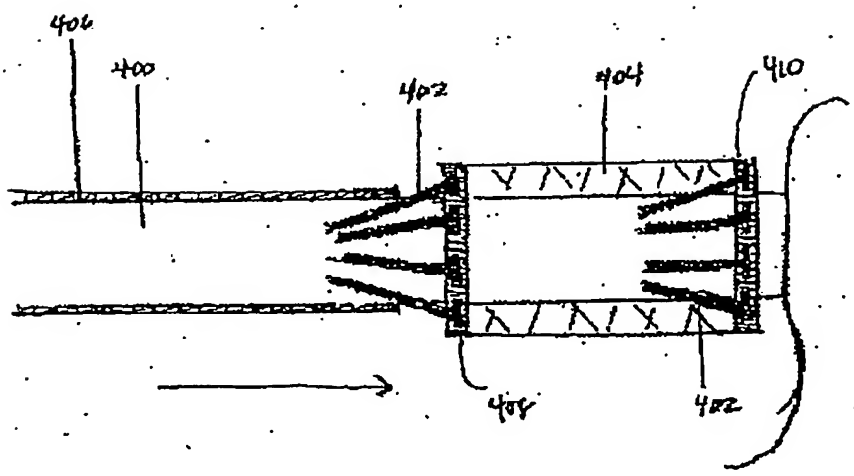


Figure 3G3

FIGURE 4



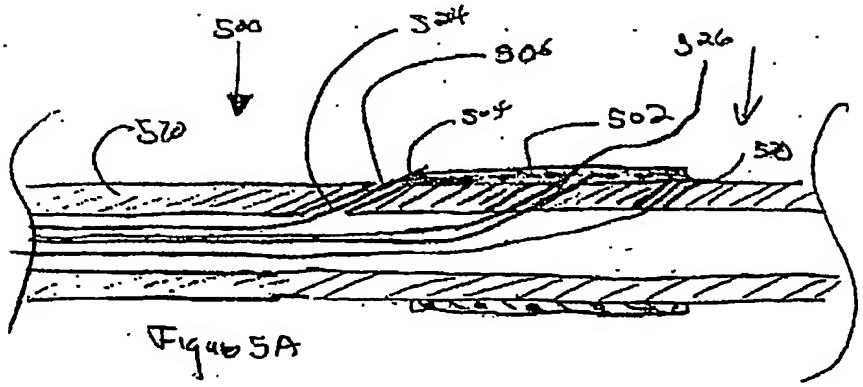


Figure 5A

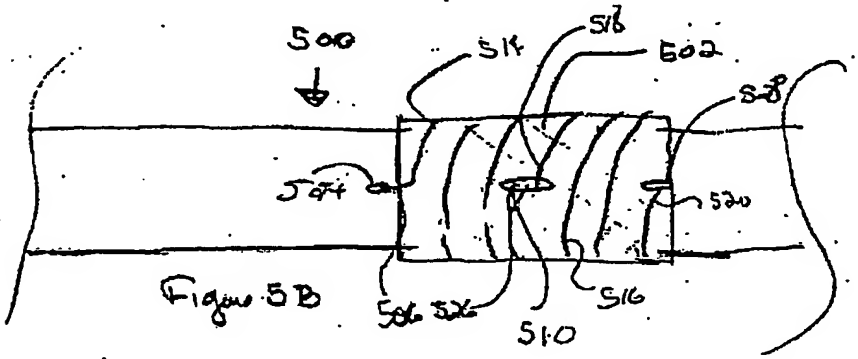


Figure 5B

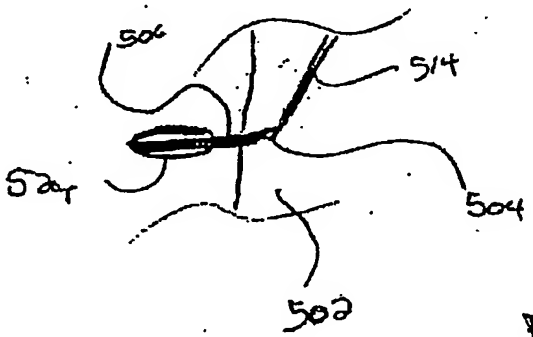


Figure 6C

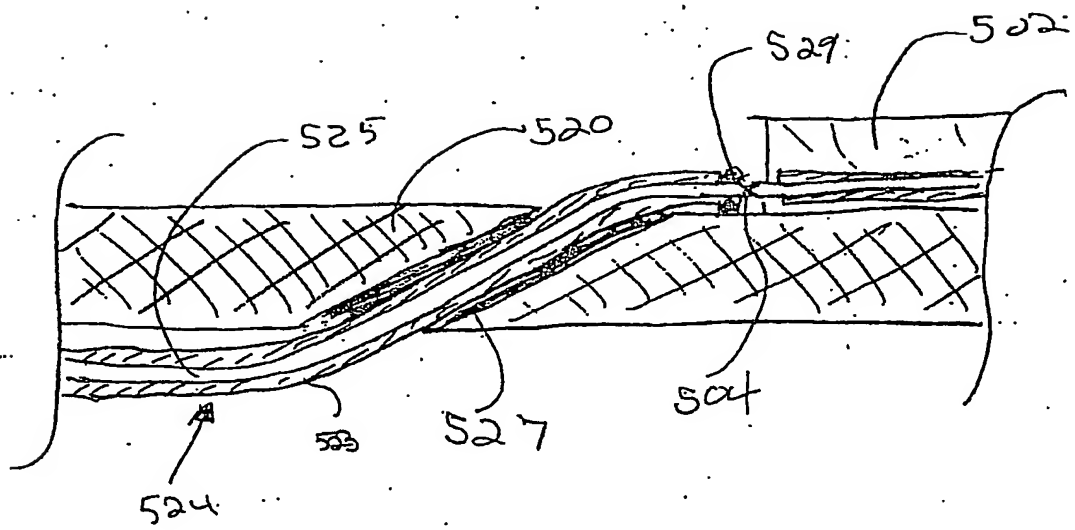


Figure 5D

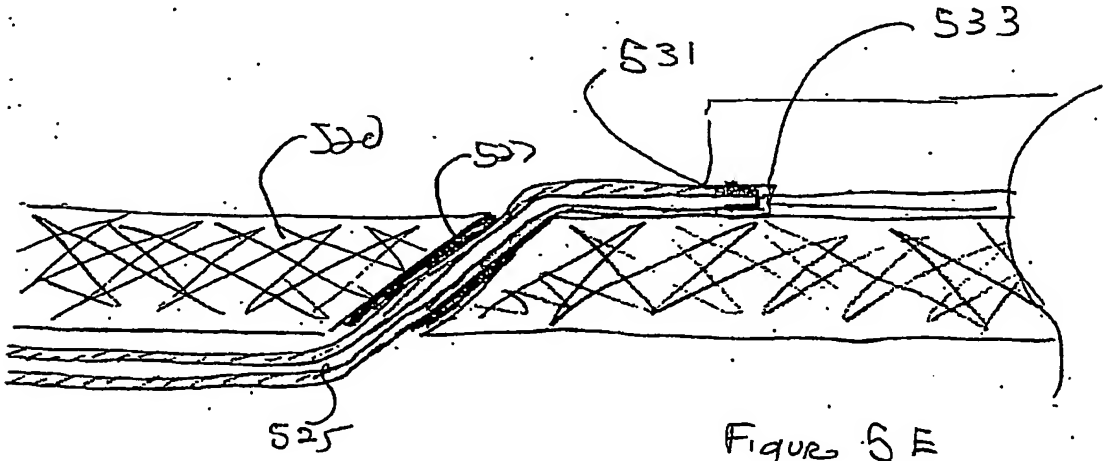


Figure 5E

FIGURE 6A

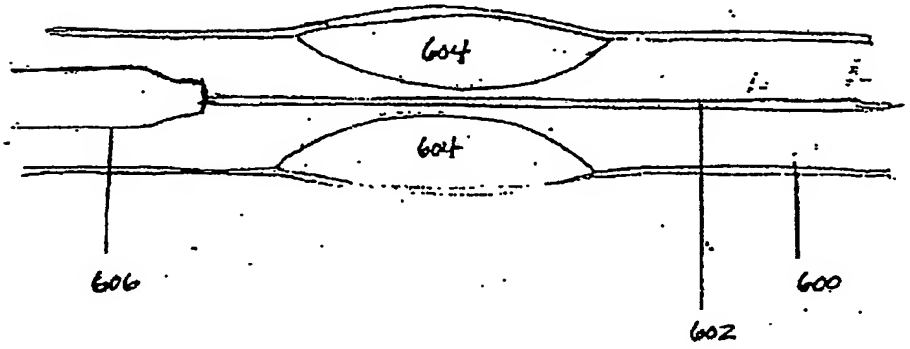


FIGURE 6B

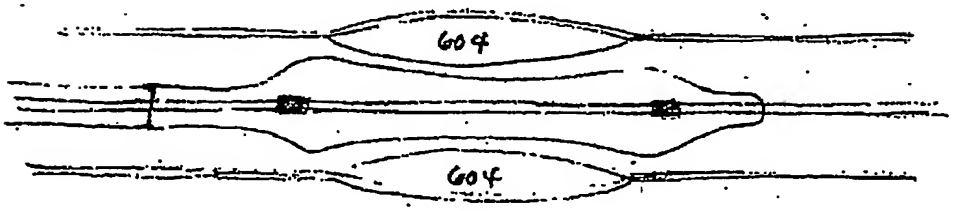


FIGURE 6C

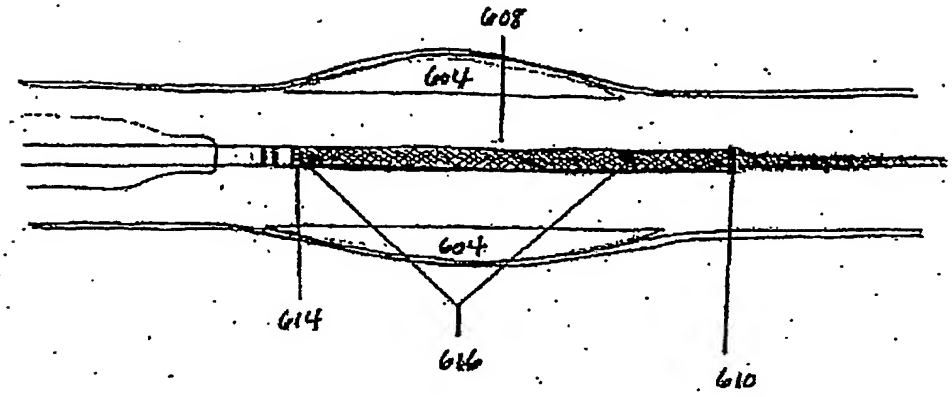


FIGURE 6D